



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q67472

Hajime NAWATA, et al.

Appln. No.: 10/029,862

Group Art Unit: 1651

Confirmation No.: 4019

Examiner: Jon P. WEBER

Filed: December 31, 2001

For: METHOD FOR IDENTIFYING ENDOCRINE DISRUPTORS AND KIT FOR
CARRYING OUT THE SAME

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Hajime Nawata, hereby declare and state:

THAT I am a citizen of Japan;

THAT I have been employed by Kyushu University since April, 1967, where I
hold a position as Professor in the Department of Medicine and Bioregulatory Science,

THAT I am a co-author of (1) Biochem. Biophys. Res. Comm., 289, 198-204 (2001),
(2) Endocrinology, 142, 437-445 (2001), and (3) Mol. Cell. Endocrin., 181, 239-248 (2001), and

THAT I am a co-inventor of claims 1-6 of the above-identified application; and

I, Dr. Toshihiko Yanase, hereby declare and state:

THAT I am a citizen of Japan;

THAT I have been employed by Kyushu University since May, 1980, where I hold a
position as Assistant Professor in the Department of Medicine and Bioregulatory Science,

THAT I am a co-author of (1) Biochem. Biophys. Res. Comm., 289, 198-204 (2001), (2) Endocrinology, 142, 437-445 (2001), and (3) Mol. Cell. Endocrin., 181, 239-248 (2001), and

THAT I am a co-inventor of claims 1-6 of the above-identified application.

In order to demonstrate that although Masayuki Saitoh, Hidetaka Morinaga, Makito Tanabe, Yi-Ming Mu, Yoshihiro Nishi, Masatoshi Nomura, Taijiro Okabe, Kiminobu Goto, and Ryoichi Takayanagi are co-authors with us of Biochem. Biophys. Res. Comm., 289, 198-204 (2001), they are not co-inventors of the invention disclosed and claimed in the above-identified application, we further declare and state:

Masayuki Saitoh, Hidetaka Morinaga, Makito Tanabe, Yi-Ming Mu, Yoshihiro Nishi, Masatoshi Nomura, Taijiro Okabe, Kiminobu Goto, and Ryoichi Takayanagi were acting at our behest and direction in the research effort. They did not participate in the conception of the invention claimed in the above-identified application.

In order to demonstrate that although Yoshihiro Nishi, Yi-Ming Mu, Koichi Oba, Isao Ichino, Masayuki Saitoh, Masatoshi Nomura, Chizu Mukasa, Taijiro Okabe, Kiminobu Goto, Ryoichi Takayanagi, Yoshiko Kashimura, and Masafumi Haji are co-authors with us of Endocrinology, 142, 437-445 (2001), they are not co-inventors of the invention disclosed and claimed in the above-identified application, we further declare and state:

Yoshihiro Nishi, Yi-Ming Mu, Koichi Oba, Isao Ichino, Masayuki Saitoh, Masatoshi Nomura, Chizu Mukasa, Taijiro Okabe, Kiminobu Goto, Ryoichi Takayanagi, Yoshiko Kashimura, and Masafumi Haji were acting at our behest and direction in the research effort. They did not participate in the conception of the invention claimed in the above-identified application.

In order to demonstrate that although Yi-Ming Mu, Yoshihiro Nishi, Ryoichi Takayanagi, and Kiminobu Goto are co-authors with us of Mol. Cell. Endocrin., 181, 239-248 (2001), they are not co-inventors of the invention disclosed and claimed in the above-identified application, we further declare and state:

Yi-Ming Mu, Yoshihiro Nishi, Ryoichi Takayanagi, and Kiminobu Goto were acting at our behest and direction in the research effort. They did not participate in the conception of the invention claimed in the above-identified application.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 08/05/2004

Hajime Nawata
Hajime Nawata

Date: 08/05/2004

Toshihiko Yanase
Toshihiko Yanase



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STATEMENT OF AVAILABILITY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, OTSUKA PHARMACEUTICAL CO., LTD., do depose, declare and state that:

We are the Assignee of the entire right, title and interest of the invention described and claimed in the above-identified application, as evidenced by the Assignment recorded on April 19, 2002, at REEL 012820, FRAME 0506.

We agree that upon allowance and issuance of the above-identified application into a United States Patent, restriction on availability of:

KGN cell line, assigned FERM-8171

which is designated in the specification of the above-identified application and was deposited under the terms of the Budapest Treaty at the International Patent Organism Depository of the NIAIST in Japan on August 29, 2002, will be irrevocably removed.

STATEMENT OF AVAILABILITY
U.S. PATENT No. 10/029,862

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We agree that the above-identified cell line designated in the above-identified application will be maintained for a period of 30 years or 5 years after the last request for the deposit or for the effective life of any patent which issues on the above-identified application, whichever is longer;

We agree that if the deposit becomes non-viable, it will be replaced; and

We also assure access to the deposit to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

OTSUKA PHARMACEUTICAL CO., LTD.

Date: April 20, 2004

Name: 

Name: Kazuhiro Tomita

Title: Senior Operating Officer